

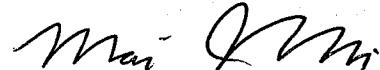
**PATENT**

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant:	Kenneth Gall, et al.	Examiner:	Jan Christopher Merene
Serial No.:	10/598,080	Group Art Unit:	3733
Filed:	September 7, 2006	Docket No.:	076775.011002
Customer No.:	37705	Confirmation No.:	9897
Title:	A GRAFT FIXATION DEVICE AND METHOD		

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Name: Marilyn Morris

**APPELLANT'S BRIEF**

MAIL STOP: APPEAL BRIEF - PATENTS  
Commissioner for Patents  
Post Office Box 1450  
Alexandria, Virginia 22313-1450

Sir:

This Appeal Brief is in furtherance of the Notice of Appeal in this case, timely filed on December 2, 2010. Appellant hereby appeals to the Board from the decision of the examiner in the Final Office Action mailed September 28, 2010, responsive to Appellant's amendment filed on July 22, 2010. Claims 46, 51, 52, 55, 56 and 139-141 are on appeal, each depending directly or indirectly from claim 46. Appellant requests a two-month extension of time under 37 CFR §136(a) for the filing of this Brief, in response to the Notice of Panel Decision from Pre-Appeal Brief Review, mailed on January 18, 2011. This Brief is accompanied by authorization to charge the requisite fee set forth in 37 CFR § 41.20(b)(2) in the amount of \$270.00 and the extension of time fee per 37 CFR §17(a) in the amount of \$245.00 as well as any additional fees that may be due to Deposit Account 502775.

## **REAL PARTY IN INTEREST**

The real parties in interest in this appeal is the Regents of the University of Colorado, the assignee of record, along with MedShape Solutions, Inc., the exclusive licensee of the application.

## **RELATED APPEALS AND INTERFERENCES**

There are no appeals or interferences that will directly affect, or be directly affected by, or have a bearing on the Board's decision in this appeal.

## **STATUS OF CLAIMS**

Claims on appeal are claims 46, 51, 52, 55, 56 and 139-141, as amended in an Amendment filed on July 22, 2010. Claims 1-45, 47-50, 53-54, and 57-138 had previously been canceled. The rejected claims on appeal are set forth in Appendix A of this Brief. These claims were rejected for a second time under 35 U.S.C. §103(a) in the Final Office Action mailed September 28, 2010. This appeal followed on December 2, 2010. Applicant also filed a Pre-Appeal Brief Request For Review on December 2, 2010 and, after the Review, the reviewing panel concluded that the issues remained for appeal in a decision mailed January 18, 2011. No claim amendments to the claims on appeal have been made since the issuance of the Final Office Action on September 28, 2010. Section IX below recites the claims as currently entered/pending.

## **STATUS OF AMENDMENTS**

An amendment was filed on July 22, 2010 in response to a Non-Final Office Action dated February 22, 2010. This amendment was entered by the examiner as indicated in the Final Office Action mailed September 28, 2010. All amendments submitted during prosecution of this application have been entered and no amendment has been filed subsequent to the Final Office Action mailed September 28, 2010.

**SUMMARY OF CLAIMED SUBJECT MATTER**

Appellant's sole independent Claim 46 calls for a method that at least includes (1) inserting a cable member into a recess in a bone, (2) inserting a retention device containing a shape memory polymer into the recess while the shape memory polymer is in a temporary pre-implantation shape due to a shape memory effect of the shape memory polymer. The method also at least includes (3) positioning the retention device in the recess while the shape memory polymer is in the temporary pre-implantation shape such that the retention device contacts the cable member and the bone, and (4) causing the shape memory polymer to change its shape through the shape memory effect from the temporary pre-implantation shape toward an unconstrained shape of the shape memory polymer, thereby fixing the cable member to the bone with the retention device.

The following Table identifies each claim element and limitation, with the corresponding page and line number in Appellant's specification and drawing providing support thereof, as is required by 37 CFR §41.37(c)(1)(v).

<b>Application No. 10/598,080</b>	
<b>Claim</b>	<b>Exemplary Support in Specification</b>
<b>Claim 46:</b> A method comprising: inserting a cable member into a recess in a bone;	Fig. 1
inserting a retention device containing a shape memory polymer into the recess while the shape memory polymer is in a temporary pre-implantation shape due to a shape memory effect of the shape memory polymer;	Paragraphs [0059], [0065], [0076]

Application No. 10/598,080	
Claim	Exemplary Support in Specification
positioning the retention device in the recess while the shape memory polymer is in the temporary pre-implantation shape such that the retention device contacts the cable member and the bone; and	Fig. 1; paragraphs [0049], [0050], [0058], [0059]
causing the shape memory polymer to change its shape through the shape memory effect from the temporary pre-implantation shape toward an unconstrained shape of the shape memory polymer, thereby fixing the cable member to the bone with the retention device.	Paragraphs [0058], [0059], [0065]

### GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

The rejections of claims 46, 51, 52, 55, 56, and 139-141 are based upon the following references:

**Dovesi:** U.S. Patent Application Publication No. 2002/0165547

**Li:** U.S. Patent Application Publication No. 2002/0165547

**Lendlein:** *Biodegradable, Elastic Shape-Memory Polymers for Potential Biomedical Applications*, Science, Vol.. 296, pp. 1673-1676 (May 31, 2002)

**Chan:** U.S. Patent Application Publication No. 2002/0188298

**Boneau:** U.S. Patent No. 5,879,382

A list of grounds of rejections to be reviewed on appeal is provided below:

**Ground 1.** Claims 46, 51, 55, and 139 are rejected under 35 U.S.C. §103(a) as being unpatentable over Dovesi in view of Lendlein.

**Ground 2.** Claim 52 is rejected under 35 U.S.C. §103(a) as being unpatentable over Dovesi in view of Lendlein and Chan.

**Ground 3.** Claims 140-141 are rejected under 35 U.S.C. §103(a) as being unpatentable over Dovesi in view of Lendlein and Boneau.

**Ground 4.** Claims 46 and 56 are rejected under 35 U.S.C. §103(a) as being unpatentable over Li in view of Lendlein.

## ARGUMENT

### Grounds 1-3: Claims 46, 51, 52, 55, and 139-141

Claim 46 stands finally rejected as unpatentable under 35 U.S.C. §103(a) over Dovesi in view of Lendlein. Applicant hereby elects to have the patentability of claims 51, 52, 55 and 139-141 stand or fall in this appeal with the patentability of claim 46.

[1] THE EXAMINER'S REJECTION OF CLAIM 46 FAILS TO ADDRESS ALL OF THE ELEMENTS AND LIMITATIONS OF CLAIM 46

In presenting a proper rejection under 35 U.S.C. §103, the examiner must compare the references to the claims and set forth any proposed modifications to the references necessary to arrive at the language of the claim. MPEP §706.02(j) ("Contents of a 35 U.S.C. 103 Rejection").

After indicating that the rejection is under 35 U.S.C. 103, the examiner should set forth in the Office action:

(A) the relevant teachings of the prior art relied upon, preferably with reference to the relevant column or page number(s) and line number(s) where appropriate,

(B) the difference or differences in the claim over the applied reference(s),

(C) the proposed modification of the applied reference(s) necessary to arrive at the claimed subject matter, and

(D) an explanation as to why the claimed invention would have been obvious to one of ordinary skill in the art at the time the invention was made.

*Id.* Furthermore, the examiner must explain the basis of the rejection of the claims so that “the applicant can be given fair opportunity to reply.” *Id.*

In the Final Office Action, the examiner has neither addressed all of the limitations of Claim 46 nor has the examiner set forth his proposed modifications to the references needed to arrive at Claim 46. Therefore, the examiner has failed to meet the requirements for a proper rejection of Claim 46 under 35 U.S.C. §103. The improper rejection has not given Applicant a fair opportunity to reply because the basis for the examiner’s rejection of Claim 46 remains unexplained and unclear. Simply put, without a proper rejection that addresses all of the limitations of Claim 46, Applicant cannot formulate a reply and move prosecution forward.

The examiner first rejected original Claim 46 as anticipated by Dovesi in the Non-Final Office Action. Applicant then attempted to further prosecution through an in-person interview between the examiner, the inventor, and the undersigned counsel wherein several potential claim revisions were discussed. Thereafter, Applicant filed significant claim revisions in response to the Non-Final Office Action, and successfully overcame the rejection of Claim 46 based on Dovesi. The examiner again rejected Claim 46 in the Final Office Action as obvious over a combination of Dovesi and Lendlein, but the examiner only addressed a fraction of the amended portions of Claim 46. Specifically, the examiner’s rejection of Claim 46 in the Final Office Action does not address at least two limitations of Claim 46 in their entirety:

positioning the retention device in the recess while the shape memory polymer is in the temporary pre-implantation shape such that the retention device contacts the cable member and the bone; and

causing the shape memory polymer to change its shape through the shape memory effect from the temporary pre-implantation shape toward an unconstrained shape of the shape memory polymer, thereby fixing the cable member to the bone with the retention device.

Without addressing these two limitations, the examiner’s rejection of Claim 46 is improper and does not give Applicant a fair opportunity to reply. Applicant cannot fairly reply to the rejection in the Final Office Action because the rejection does not apprise Applicant of the

grounds of the rejection and therefore the Applicant is left to speculate why the examiner has rejected the amended Claim 46. Therefore, Applicant respectfully requests that the examiner's rejection of Claim 46 based on Dovesi and Lendlein be reversed.

[2] THE EXAMINER MISREADS DOVESI

In addition to failing to properly address each limitation of Claim 46, the examiner's rejection of Claim 46 based on Dovesi and Lendlein is based on a misreading of Dovesi.

Dovesi teaches a helical device 6 that mates with a screw device 7 and the method of trapping a tendon 4 between the two devices in order to fix the tendon. Dovesi, paragraphs 19-23. Dovesi continues to describe that the device is completed by a washer 16 to block the end portions of the tendon 4 by abutting the bone cortex. Dovesi, paragraphs 24-26. Dovesi then describes advantages of using the device, namely that the tendon 4 "follows a winding path" through the helical device 6 when it is mated with the screw device 7, and that the tendon is thereby fixed to the bone. Dovesi, paragraphs 27-28.

After Dovesi's described system (paragraphs 19-28) of interlocking devices that each work without any shape-changing features, let alone shape-memory features, Dovesi discloses, in passing, some possible materials for the device.

[0029] In the practical execution of the device according to the invention, the shapes and the dimensions of the components may vary according to requirements.

[0030] The device can be made of metal (titanium or steel) or of composite, absorbable, or shape-memory materials.

Dovesi, 3:35-39. Therefore, Dovesi only mentions shape-memory materials as an alternative material for Dovesi's devices, none of which are described as changing shape.

Regardless, the examiner repeatedly argues that Dovesi teaches "activating the shape memory material (as seen in Fig [1] and see paragraph 25-26, 30)." However, there is no such

teaching or suggestion of activating a shape memory material in the Dovesi reference, such as may be performed to change shape of the material, and Dovesi fails to disclose any of the effects of activating a shape memory material, such as changing shape and/or developing forces against a constraint. Furthermore, Dovesi fails to disclose how any shape change would be used by the Dovesi device. Indeed, the function of Dovesi's device, that of fixing tendon to bone, operates entirely without a change in shape. Therefore, the examiner cannot rely on Dovesi for disclosing either the previous claim limitation "activating the shape memory material" or the present claim limitation "causing the shape memory polymer to change its shape."

[3] THE EXAMINER IMPROPERLY COMBINES DOVESI WITH LENDElein

The examiner improperly combines Dovesi with Lendlein because (1) there is no suggestion or motivation in either reference to combine Dovesi with Lendlein, (2) the references teach away from combining with each other and (3) the combination of Dovesi with Lendlein would render the Dovesi device inoperable for the purpose of fixing a tendon to bone. MPEP §§ 2143.01(V), 2145(X)(D).

[3A] There is no motivation to combine Dovesi and Lendlein

As described above, Dovesi only teaches shape-memory materials as an alternative material for the components of the Dovesi device that fix tendon to bone in their original and unchanged shapes. There is no suggestion in Dovesi for using any shape-changing properties of the shape-memory materials to fix tendon to bone. Therefore, there is no suggestion or motivation in Dovesi to combine its teachings with the shape-changing shape memory polymer teachings of Lendlein to arrive at the method of claim 46 for fixing a tendon to bone.

The examiner points to Lendlein's enumerated benefits of a shape memory polymer's "reduced size" in performing surgery with a smaller incision based on the shape memory polymer's ability to regain a "bulkier" shape upon activation. However, this provides no motivation to combine with Dovesi, which nowhere discusses reducing the size of the devices or even how to account for the devices changing shape when fixing a tendon to a bone. Instead,

Lendlein teaches use of low-modulus shape memory polymers with moduli that are compatible with the moduli of lumens or other soft tissues.

[3B] Lendlein teaches away from combination with Dovesi

Dovesi describes a device for fixing tendon to bone. By contrast, Lendlein teaches the use of shape memory polymers for their low moduli and superior compliance that “resembles” soft tissues:

**the third cycle. Ni-Ti alloys show stresses in the range of 200 to 400 MPa during shape-memory transition, whereas the shape-memory thermoplastics produce stresses in the range between 1 and 3 MPa, depending on the hard segment content (23). The lower value for shape-memory polymers resembles the mechanical stresses in soft tissue (24).**

(Lendlein p. 1675.)

Lendlein further emphasizes the use of shape memory polymers for low force environments, such as sutures of soft tissues in arthroscopic surgery, through experimental results of a 1.6N tension on the suture (or 0.36 pounds of force) which does not tear the soft tissue. *Id.* This is significantly outside the range of forces required to fix a tendon to bone. For example, Applicant discloses 831.9N (or 187 pounds of force) as the average pull-out tensile strength of a bone fixation system of Applicant’s disclosure. (See Applicant’s Fig. 20a.)

Therefore, the examiner’s rejections based on combinations of Lendlein with Dovesi are improper and should be reversed because the rejections do not consider the entirety of the references or the significant aspects teaching away from their combination and the combinations are therefore improper. MPEP §§ 2141.02, 2145(X)(D).

[3C] A combination of Lendlein with Dovesi would fail to operate as claimed by Applicant

If the shape-changing shape memory polymers of Lendlein were combined with the static device of Dovesi, the resulting device would fail to meet the claim limitations and would fail to produce the claimed result, namely the combined device would fail to fix tendon to bone.

Dovesi does not teach or suggest how using shape memory materials, such as Lendlein’s

polymers, would differ from using common metals such as titanium or steel. Therefore, a reader would be left to guess how to incorporate Lendlein's low-modulus polymers into Dovesi's device to create the necessary forces to fix a tendon to bone.

[4] CONCLUSION: THE REJECTION OF CLAIM 46 OVER DOVESI IN VIEW OF LENDELIN IS IMPROPER AND SHOULD BE REVERSED

The rejection of Claim 46 over Dovesi in view of Lendlein fails to address the limitations of Claim 46 and, therefore, fails to meet the requirements of a proper rejection under 35 U.S.C. § 103. Without addressing the limitations of Claim 46, the improper rejection of Claim 46 does not give Applicant a fair opportunity to reply and advance prosecution.

Furthermore, the Dovesi and Lendlein references, properly viewed together and in their entirety, fail to disclose or suggest Applicant's claimed features. Moreover, the cited references actually teach away the combination and the combined device would fail to operate. Therefore, Claim 46 is patentable over the cited references, and the rejection of Claim 46 under 35 U.S.C. §103 should be reversed.

#### **Ground 4: Claims 46 and 56**

Claim 46 stands finally rejected as unpatentable under 35 U.S.C. §103(a) over Li in view of Lendlein. Applicant hereby elects to have the patentability of Claim 56 stand or fall in this appeal with the patentability of Claim 46.

[1] THE EXAMINER'S REJECTION OF CLAIM 46 FAILS TO ADDRESS ALL OF THE ELEMENTS AND LIMITATIONS OF CLAIM 46

In presenting a proper rejection under 35 U.S.C. §103, the examiner must compare the references to the claims and set forth any proposed modifications to the references necessary to arrive at the language of the claim. MPEP §706.02(j) ("Contents of a 35 U.S.C. 103 Rejection").

After indicating that the rejection is under 35 U.S.C. 103, the examiner should set forth in the Office action:

- (A) the relevant teachings of the prior art relied upon, preferably with reference to the relevant column or page number(s) and line number(s) where appropriate,
- (B) the difference or differences in the claim over the applied reference(s),
- (C) the proposed modification of the applied reference(s) necessary to arrive at the claimed subject matter, and
- (D) an explanation as to why the claimed invention would have been obvious to one of ordinary skill in the art at the time the invention was made.

*Id.* Furthermore, the examiner must explain the basis of the rejection of the claims so that “the applicant can be given fair opportunity to reply.” *Id.*

In the Final Office Action, the examiner has neither addressed all of the limitations of Claim 46 nor has the examiner set forth his proposed modifications to the references needed to arrive at Claim 46. Therefore, the examiner has failed to meet the requirements for a proper rejection of Claim 46 under 35 U.S.C. §103. The improper rejection has not given Applicant a fair opportunity to reply because the basis for the examiner’s rejection of Claim 46 remains unexplained and unclear. Simply put, without a proper rejection that addresses all of the limitations of Claim 46, Applicant cannot formulate a reply and move prosecution forward.

The examiner first rejected original Claim 46 as anticipated by Li in the Non-Final Office Action. Applicant then attempted to further prosecution through an in-person interview between the examiner, the inventor, and the undersigned counsel wherein several potential claim revisions were discussed. Thereafter, Applicant filed significant claim revisions in response to the Non-Final Office Action, and successfully overcame the rejection of Claim 46 based on Li. The examiner again rejected Claim 46 in the Final Office Action as obvious over a combination of Li and Lendlein, but the examiner only addressed a fraction of the amended portions of Claim 46. Specifically, the examiner’s rejection of Claim 46 in the Final Office Action does not address at least two limitations of Claim 46 in their entirety:

positioning the retention device in the recess while the shape memory polymer is in the temporary pre-implantation shape such that the retention device contacts the cable member and the bone; and

causing the shape memory polymer to change its shape through the shape memory effect from the temporary pre-implantation shape toward an unconstrained shape of the shape memory polymer, thereby fixing the cable member to the bone with the retention device.

Without addressing these two limitations, the examiner's rejection of Claim 46 is improper and does not give Applicant a fair opportunity to reply. Applicant cannot fairly reply to the rejection in the Final Office Action because the rejection does not apprise Applicant of the grounds of the rejection and therefore the Applicant is left to speculate why the examiner has rejected the amended Claim 46. Therefore, Applicant respectfully requests that the examiner's rejection of Claim 46 based on Li and Lendlein be reversed.

[2] THE EXAMINER MISREADS LI

In addition to failing to properly address each limitation of Claim 46, the examiner's rejection of Claim 46 based on Li and Lendlein is based on a misreading of Li.

Li teaches a device using 8 or 12 anchoring barbs (36) made of shape memory alloy. Li, 7:15-31 and 8:1-25. The shape memory alloy barbs (36) are elastically deformed when the device is installed from a curved form to a straight form laying flat in the channels 34 on the outside of the device. Li, 4:35-45. This elastic deformation uses a property of a shape memory alloy called either pseudo-elasticity or super-elasticity, whereby the shape memory alloy provides a non-linear (i.e., Force  $\neq$  Constant\*Displacement) and immediately responsive force to elastic deformation, rather than a delayed or memorized response due to activation. Li teaches that using the pseudo-elastic behavior allows the barbs to "resiliently 'spring back' toward [the barb's] normal, outwardly projecting position so as to prevent the anchor from withdrawing back out the bone tunnel." Li, 4:28-31. In other words, Li uses the immediate responsive force, a feature not used in shape memory alloys with stored deformations, to have the barbs "resiliently 'spring back'" and fix the tendon to the bone. "At the same time [as the barbs are deflected

inwardly], however, the anchor's barbs will prevent the anchor from being withdrawn from the bone tunnel in the direction of its entry.” Li, 4:43-45. Therefore, while Li's device may use a shape memory alloy in its device, nevertheless, Li fails to teach or disclose any use of the barb in any memorized shape.

[3] THE EXAMINER IMPROPERLY COMBINES LI WITH LENDLEIN

The examiner improperly combines Li with Lendlein because (1) there is no suggestion or motivation in either reference to combine Li with Lendlein, (2) the references teach away from combining with each other and (3) the combination of Li with Lendlein would render the Li device inoperable for the purpose of fixing a tendon to bone. MPEP §§ 2143.01(V), 2145(X)(D).

[3A] There is no motivation to combine Li and Lendlein

Li provides no motivation to include Lendlein's shape memory polymers with shape changes being memorized and later occurring through activation. As described above, Li only teaches shape memory alloys without any memorized shape. Li describes elastically deforming the shape memory alloys barbs and relying on the “spring back” of those barb to fix the tendon to bone. There is no motivation to substitute into Li's device the low-modulus shape memory polymers of Lendlein's disclosure which would provide significantly less forces resisting tendon separation from the bone. Lendlein, p. 1675.

Lendlein provides no motivation to include its shape memory polymers in Li's device. The examiner points to Lendlein's enumerated benefits of a shape memory polymer's “reduced size” in performing surgery with a smaller incision based on the shape memory polymer's ability to regain a “bulkier” shape upon activation. Lendlein, p. 1673-4. However, this provides no motivation to combine with Li, which teaches introducing a bulkier device with 8-12 barbs in an extended position and then elastically deforming the barbs by contact with the bone into a compressed shape.

[3B] Lendlein teaches away from combination with Li

Li describes a device for fixing tendon to bone. By contrast, Lendlein teaches the use of shape memory polymers for their low moduli and superior compliance that “resembles” soft tissues:

**the third cycle. Ni-Ti alloys show stresses in the range of 200 to 400 MPa during shape-memory transition, whereas the shape-memory thermoplastics produce stresses in the range between 1 and 3 MPa, depending on the hard segment content (23). The lower value for shape-memory polymers resembles the mechanical stresses in soft tissue (24).**

(Lendlein p. 1675.)

Lendlein further emphasizes the use of shape memory polymers for low force environments, such as sutures of soft tissues in arthroscopic surgery, through experimental results of a 1.6N tension on the suture (or 0.36 pounds of force) which does not tear the soft tissue. *Id.* This is significantly outside the range of forces required to fix a tendon to bone. For example, Applicant discloses 831.9N (or 187 pounds of force) as the average pull-out tensile strength of a bone fixation system of Applicant's disclosure. (See Applicant's Fig. 20a.)

Therefore, the examiner's rejections based on combinations of Lendlein with Li are improper and should be reversed because the rejections do not consider the entirety of the references or the significant aspects teaching away from their combination and the combinations are therefore improper. MPEP §§ 2141.02, 2145(X)(D).

[3C] A combination of Lendlein with Li would fail to operate as claimed by Applicant

If the shape memory polymers of Lendlein were combined with the Li device, the combined device would fail to fix tendon to bone. Li teaches a device using 8 or 12 anchoring barbs (36) with a diameter of 0.03 inches (0.762 mm) or an area of 0.000707 inches<sup>2</sup> (0.456 mm<sup>2</sup>) to be fixed within a bone tunnel. If one of Li's devices were created using the shape memory polymer teachings of Lendlein, the barbs would create on the bone tunnel only a maximum of 1.37 N of force per barb (3 MPa x 0.456 mm<sup>2</sup>/1,000,000) or a total of 16.4 N of force among all 12 barbs, which is equal to about 3.7 pounds of force. Simply put, the 3.7

pounds of force capable of being generated by a combined device would be entirely insufficient for fixing tendon to bone.

[4] CONCLUSION: THE REJECTION OF CLAIM 46 OVER LI IN VIEW OF LENDEIN IS IMPROPER AND SHOULD BE REVERSED

The rejection of Claim 46 over Li in view of Lendlein fails to address the limitations of Claim 46 and, therefore, fails to meet the requirements of a proper rejection under 35 U.S.C. § 103. Without addressing the limitations of Claim 46, the improper rejection of Claim 46 does not give Applicant a fair opportunity to reply and advance prosecution.

Furthermore, the Li and Lendlein references, properly viewed together and in their entirety, fail to disclose or suggest Applicant's claimed features. Moreover, the cited references actually teach away the combination and the combined device would fail to operate. Therefore, Claim 46 is patentable over the cited references, and the rejection of Claim 46 under 35 U.S.C. §103 should be reversed.

## **CLAIMS APPENDIX**

A complete listing of the claims involved in this appeal is attached hereto as Appendix A.

## **EVIDENCE APPENDIX**

None.

## **RELATED PROCEEDINGS APPENDIX**

Appellant states that there are no relevant related proceedings and therefore no Related Proceeding Appendix is hereby attached.

## CONCLUSION

The examiner's rejections of Claim 46 are improper because the rejections fail to address all of the elements and limitations of Claim 46. The examiner's rejections of Claim 46 fail to present a *prima facie* case of obviousness because the cited references do not disclose the limitations of Claim 46, either alone or in combination. In addition, the examiner's rejections rely on improper combinations of the cited references. Therefore, the examiner has failed to establish a valid obviousness rejection under 35 USC §103(a) as to any of Appellant's pending Claims. Reversal of the examiner's rejections and allowance of all Claims on appeal are therefore respectfully solicited.

Respectfully submitted,

  
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### **Included attachments:**

Claims Appendix: Claims on Appeal

Evidence Appendix: None

Related Proceedings Appendix: None

## APPENDIX A

### Claims on Appeal:

1-45. (Cancelled).

46. (Previously presented) A method comprising:

inserting a cable member into a recess in a bone;

inserting a retention device containing a shape memory polymer into the recess while the shape memory polymer is in a temporary pre-implantation shape due to a shape memory effect of the shape memory polymer;

positioning the retention device in the recess while the shape memory polymer is in the temporary pre-implantation shape such that the retention device contacts the cable member and the bone; and

causing the shape memory polymer to change its shape through the shape memory effect from the temporary pre-implantation shape toward an unconstrained shape of the shape memory polymer, thereby fixing the cable member to the bone with the retention device.

47-50. (Cancelled)

51. (Original) The method of claim 46, wherein the cable member is selected from an animal tissue, a synthetic fiber, a natural fiber, a polymer, a metallic wire, a bundle, and a composite.

52. (Original) The method of claim 51, wherein the animal tissue is human soft tissue.

53-54. (Cancelled)

55. (Original) The method of claim 46, wherein the inserting the cable member operation precedes the inserting the retention device operation.

56. (Original) The method of claim 46, wherein the inserting the cable member operation is performed simultaneously with the inserting the retention device operation.

57-138. (Cancelled).

139. (Previously presented) The method of claim 46, wherein causing the shape memory polymer to change shape through the shape memory effect is performed by heating, and wherein the heating comprises a transfer of heat from the bone to the shape memory polymer.

## APPENDIX A

140. (Previously Presented) The method of claim 46, wherein causing the shape memory polymer to change shape through the shape memory effect is performed by heating, and wherein the heating comprises flooding the retention device with a liquid bath.

141. (Previously Presented) The method of claim 46, wherein causing the shape memory polymer to change shape through the shape memory effect is performed by heating, and wherein the heating comprises a transfer of heat from the bone to the shape memory polymer, and flooding the retention device with a liquid bath.